



Constructing “Sound Science” and “Good Epidemiology”: Tobacco, Lawyers, and Public Relations Firms

| Elisa K. Ong, MD, MS, and Stanton A. Glantz, PhD

The tobacco industry has attacked “junk science” to discredit the evidence that secondhand smoke—among other environmental toxins—causes disease. Philip Morris used public relations firms and lawyers to develop a “sound science” program in the United States and Europe that involved recruiting other industries and issues to obscure the tobacco industry’s role. The European “sound science” plans included a version of “good epidemiological practices” that would make it impossible to conclude that secondhand smoke—and thus other environmental toxins—caused diseases.

Public health professionals need to be aware that the “sound science” movement is not an indigenous effort from within the profession to improve the quality of scientific discourse, but reflects sophisticated public relations campaigns controlled by industry executives and lawyers whose aim is to manipulate the standards of scientific proof to serve the corporate interests of their clients.

THE TERMS “SOUND SCIENCE” and “junk science” have increasingly appeared in the media, medical literature,^{1,2} and litigation.³ Industries—those responsible for products ranging from silicone gel breast implants^{4,5} to hormone-treated beef⁶ to secondhand smoke⁷—claim to be victimized by lawsuits and regulations based on “junk science,”^{2,8} while the scientific, public health, and regulatory communities claim their actions are based on “sound science.”^{9–12}

The tobacco industry has always contested the evidence that secondhand smoke endangers nonsmokers^{13–17}; during the last decade the Philip Morris (PM) tobacco company appropriated the “sound science” concept to attack studies on secondhand smoke. To deal with the tobacco industry’s lack of credibility, it developed “sound science” coalitions involving other industries opposed to regulation to support its position, similar to smokers’ rights^{18,19} and restaurant association^{20,21} front groups. PM also mounted a sophisticated public relations campaign to promote “good epidemiology practices” (GEP) to shape the standards of scientific proof to make it impossible to “prove” that secondhand smoke—among many other environmental toxins—is dangerous.

We analyzed tobacco industry documents made public as a result of litigation in the United States and available on the Internet in an online repository to

which documents are continually added as additional and unrelated legal cases are resolved. The documents cited in the reference list were originally accessed between January 2000 and May 2001. Search terms included “IARC,” “TASSC,” “sound science,” “junk science,” “GEP,” and the names of key players. We did not use documents from a related depository covering British American Tobacco in Guildford, England, because of the depository’s practical inaccessibility to researchers.²² If we had used the Guildford documents, they probably would have contributed to a broader story.

PHILIP MORRIS’S “SOUND SCIENCE” ORGANIZATION IN THE UNITED STATES

PM began its “sound science” program in 1993 to stimulate criticism of the 1992 US Environmental Protection Agency (EPA) report,²³ which identified secondhand smoke as a Group A human carcinogen. Ellen Merlo (vice president, PM Corporate Affairs) wrote to William Campbell (chairman, PM USA):

OBJECTIVES

Our overriding objective is to discredit the EPA report and to get the EPA to adopt a standard for risk assessment for all products.

Concurrently, it is our objective to prevent states and cities, as well as businesses from passing smoking bans.

And finally, where possible we will proactively seek to pass

accommodation legislation with preemption.

STRATEGIES

To form local coalitions to help us educate the local media, legislators and the public at large about the dangers of “junk science” and to caution them from taking regulatory steps before fully understanding the costs in both economic and human terms [emphasis added].²⁴

In February 1993, PM and its public relations firm, APCO Associates, worked to launch a “sound science” coalition in the United States, with approximately \$320 000 budgeted for the first 24 weeks.²⁴ Three months later, The Advancement for Sound Science Coalition (TASSC) had been formed.²⁵ TASSC described itself as “a not-for-profit coalition advocating the use of sound science in public policy decision making,”²⁶ even though APCO created it to help PM fight smoking restrictions.^{27,28} TASSC’s public positioning and media campaign were designed to minimize its connections with the tobacco industry^{29,30}; TASSC’s member survey mentioned only secondhand smoke among a list of other potential examples of “unsound, incomplete, or unsubstantiated science.”³¹

A broad base of issues and members was necessary to provide credibility to the new organization. Charles Lister, a lawyer at the tobacco industry’s Washington, DC, law firm, Covington & Burling, wrote, “No one would take seriously a meeting even partly sponsored by PM in which

EPA was more than one example among several. In any event, our points can be made more effectively and persuasively if EPA is discussed within a larger context.³² Lister suggested that “foods, plastics, chemicals, and packaging would be natural candidates” in broadening the scope of TASSC’s sponsors and issues beyond EPA and the tobacco industry.³²

To develop TASSC into “a broad-based and diverse national coalition,”³³ more than 20 000 recruitment letters were mailed, with 100 letters mailed to “key scientists,”³⁴ signed by TASSC’s chairman Garrey Carruthers (former Republican governor of New Mexico). The leadership and members, which included prominent scientists and policymakers^{35–37} plus representatives from corporations,^{37,38} would be provided PM’s secondhand smoke agenda suggestions through APCO but made to feel the agenda was their own.³⁹

PM hid its role⁴⁰ so successfully that when longtime tobacco industry consultant Gary Huber, then a professor at the University of Texas Health Center, received the letter inviting him to join TASSC, he contacted Tony Andrade of the PM law firm Shook, Hardy & Bacon (SH&B) to inform him that the organization might be helpful to the tobacco industry.⁴¹ Andrade, also unaware of PM’s role with TASSC, forwarded the information to PM, which subsequently “filled him in on TASSC.”⁴¹

TASSC’s overall effectiveness in serving PM’s initial goal of discrediting the EPA report may not have met PM’s expectations; by April 1994, Merlo expressed concern that, despite its \$880 000 cost in 1994,^{42,43} TASSC was not proving to be a “tool to affect leg-

islative decisions”²⁸ to stem smoking restrictions.

Even so, by 1995, a TASSC Web site was being planned with PM to distribute scientific papers and polls to support PM’s position.⁴⁴ TASSC and its Web site are now defunct, but its executive director Steve Milloy, an adjunct scholar at the Cato Institute (a libertarian think tank in Washington, DC, that has received funds from the tobacco industry⁴⁵), now produces a “junk science” Web site.⁴⁶ Milloy’s Web site continues TASSC’s original work in criticizing and “debunking” the science behind public health and environmental issues, including secondhand smoke.⁴⁶

THE EUROPEAN “SOUND SCIENCE” PROGRAM AND “GOOD EPIDEMIOLOGY PRACTICES”

PM also developed a “sound science” program in Europe to subvert⁴⁷ the effects of a large ongoing European epidemiologic study of passive smoking and lung cancer being conducted by the International Agency for Research on Cancer (IARC),⁴⁸ which the tobacco industry feared would stimulate smoking restrictions in Europe. PM sought to “develop a programme to generate support for ‘junk science’ and education on use and abuse of epidemiology, possibly through a coalition on bad science,”⁴⁹ which would prepare a skeptical environment for interpreting the study’s results. PM used the public relations firms Burson-Marsteller and APCO^{39,50–54} to address the need that “science must be managed according to clear, scientifically based criteria, e.g., good epidemiology,”⁵⁵ consistent with the industry’s interests.

PM’s interest in promoting “good epidemiology” developed after the Chemical Manufacturers Association (CMA) published its suggested “Good Epidemiology Practices” (GEP) in 1991 as a framework for “consumers of epidemiology” (policymakers and regulators) to determine the quality of a study and address poorly conducted studies.⁵⁶ The CMA’s GEP promoted the “sound science” and “good epidemiology” concepts for each step in the conduct of an epidemiologic study.^{57,58} Covington & Burling lawyer Charles Lister distributed the CMA’s GEP to PM in February 1994:

Their [CMA’s] announced goals are essentially our own. The GEP Guidelines are intended to be analogous to Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP), both of which are expressly now endorsed and required by Community law.

The GEP Guidelines themselves seem disappointingly vague to me.

...GEP is being pushed in Europe by a number of companies, including particularly Monsanto and ICI.

...I was informally told that DG V [European Union’s Directorate General for Employment, Industrial Relations and Social Affairs] is quite interested in GEP, although reticent about proposing new legislation. Nonetheless, there seems to be a realistic prospect that they might be persuaded to issue a [European] Commission Communication or other policy document.⁵⁹

PM saw the CMA’s GEP as an opportunity to promote an official epidemiologic standard that would challenge the methodology of IARC’s work.⁶⁰ Thomas Borelli (Director, PM Science and Environmental Policy), however, expressed concern that the CMA guidelines did not go far enough

to meet the tobacco industry’s needs because

... it lacks teeth and as written it does not have enough meat to help us on ETS [environmental tobacco smoke, another term for secondhand smoke]. However setting up our own standards is a good project for us and our consultant’s [sic] program. It would be good of offensive strategy for our consultant’s [sic] to be out there trying to fix epidemiology instead of being critical all the time.⁶¹

PM’s scientific personnel agreed that PM could adapt GEP to include secondhand smoke studies and that PM’s consultants, a network of scientists being financed by industry lawyers to contest the evidence that secondhand smoke caused disease,^{47,62,63} should “fix” epidemiology proactively.^{64,65} Mitch Ritter (PM Scientific Affairs) noted the obstacles, and appeal, of this approach: “It is difficult to imagine epidemiologists—or the health lobby in general—accepting this [CMA] initiative as it stands, though they will have to accept the principle of a set of good practices.”^{64,65} PM decided to appropriate the GEP movement by broadening its GEP support base to the scientific community, European government bodies, and other industries with similar concerns about low-level risks. PM’s 1994 “Legislative Guidelines on GEP” included the following:

Objective
* Impede adverse legislation

Strategy
* Endorsement by scientific world
* International gathering of world’s top epidemiologists (October)
Tool: GEP guidelines
* Expand debate to EU [European Union] political targets
* Political conference opportunities (DG V, STOA [EU Directorate General for Em-

ployment, Industrial Relations and Social Affairs; Science and Technology Office of Assessment])

* Legislative opportunities (EAC, Biomed, public health framework)

Tool: GEP resolution

* Motivate concerned industry sectors

* GEP lobby

Physical agents:

- Mobile phones, electricity (EMF)

- Computers (UV rays)

Chemical agents:

- Food (sugar, dairy, flavorings)

- Chemicals

- Metals

* Sound science lobby

Widen to

- Packaging

- Pharmaceutical

- Forestry/paper⁶⁶

PM wanted GEP guidelines to be endorsed by the scientific community, a GEP resolution to be passed through European legislation, and a GEP lobby with other industries facing regulation and a broad-based “sound science” lobby. As with the initial “sound science” efforts, the tobacco industry’s role would be minimized. The industry sought broad support of numerous endorsers on a variety of issues to provide credibility for PM’s GEP objective—to avert increased smoking restrictions.

With the help of its legal, public relations, and scientific resources, PM began drafting a GEP resolution that would be “authored” by a “sound science” coalition. In June 1994, APCO drafted a potential TASSC-sponsored list of “17 Guiding Scientific Principles,”⁶⁷ which PM found “too vague” and not supportive enough of its GEP plans.⁶⁸ SH&B drafted GEP guidelines to be sponsored by an “Executive Committee of the Sound Science Coalition” (Table 1).⁵⁴ SH&B’s GEP resolution⁵⁴ promoted the tobacco industry’s position, subsequently advocated publicly by

SH&B,⁶⁹ that odds ratios of 2 or less are highly questionable and that a statistically significant association is not strong enough evidence for causation to warrant regulatory action. (This concentration on odds ratios was not in the original CMA proposal.)

PM consultant Roger Walk restructured the GEP resolution, relying “heavily on the content of the [SH&B] drafts” to “look more like a ‘scientist’s’ version of guidelines.”^{70,71} With the relative risk for lung cancer due to passive smoking at about 1.2,^{17,23,48,72–75} and the relative risk for heart disease about 1.3,^{74–76} this standard would prevent action to protect the public from lung cancer and heart disease caused by second-hand smoke.

To obtain scientific endorsement of PM’s GEP, PM needed scientists to promote it to government bodies.⁷⁷ In June 1994, PM sought scientists to participate in a GEP seminar in Germany⁵⁴ and planned for a subsequent long-term coalition that would help criticize the IARC study.⁷⁸ Burson-Marsteller identified scientists interested in “sound science” and “good epidemiology,” but found that some scientists were concerned that corporate sponsorship—especially sponsorship by PM—would limit their scientific independence, even though Burson-Marsteller had not mentioned PM.^{79,80} In August 1994, Covington & Burling created a list of potential epidemiologists who might be approached for the GEP seminar, excluding “influential epidemiologists known to have strongly anti-tobacco views.”⁸¹

The plan to use prescreened epidemiologists may have changed just as PM was ready to introduce GEP to them.⁸² An October 1994 memo from Joanna

TABLE 1— Shook, Hardy & Bacon’s Draft GEP Resolution for a “Sound Science” Coalition⁵⁴

THE EXECUTIVE COMMITTEE RECOMMENDS that the members of the Sound Science Coalition adopt and actively promote in the scientific community at large and within their individual disciplines, appropriate and specific professional standards for epidemiological research, to be carried out by accredited individuals and institutions, reflecting the following principles:

1. The study design should clearly define all objectives and hypotheses. Possible problems in design and data interpretation should be described and the intended method for addressing each fully set out. Every effort should be made to address possible confounders to avoid the need for subsequent adjustments.
2. In case-control studies, special attention should be given to how the control group will be selected and what matching procedures will be utilized. Also, case selection should be explained with emphasis on efforts to ensure a high participation rate. A pre-calculation of required sample size should be carried out to ensure that the sample is sufficient to produce meaningful results.
3. Statements of study design should contain a description of statistical techniques. This should include underlying assumptions for distribution, variance, correlation and regression procedures. The degree to which violation of these assumptions would invalidate the analysis should be specified whenever possible.
4. Adherence to the study protocol should be as close as possible. Any deviations (e.g., errors in randomization, low participation rate, suspected confounders, possible misclassification) should be documented.
5. Special care should be given to the training and monitoring of those administering questionnaires and surveys; blinded techniques are preferred.
6. After the study is conducted, the results should be analyzed as specified by the study protocol. Two-sided hypothesis tests are encouraged. If a one-sided test is employed, this should be noted and the rationale for using it provided. The presentation of confidence intervals for the estimate of risk gives more information than a single point value with an associated p value. Generally, 95% confidence intervals are preferred.
7. An adequate description of the raw data should precede and complement formal statistical analysis. If the data are not supportive of the stated hypotheses, no further analysis is necessary. Subsequent treatment of the data should only be for hypothesis generating purposes.
8. Odds ratios of 2 or less should be treated with caution, particularly when the confidence intervals are wide. There is a likelihood that the odds ratio is artefactual and the result of problems with case or control selection, confounders or bias.
9. Meta-analysis and pooling techniques are best used for homogenous data gathered under a uniform pool.
10. Observations that are inconsistent with the main body of the data should not be excluded from the analysis.
11. Journal articles and scientific conferences are the appropriate forum for the presentation of research results. Every effort should be made to publish and report on all completed research, regardless of outcome. Only by such efforts can the entire sample of conducted research be made available to the scientific community and publication bias minimized.
12. Generally, hypotheses tests not specified by the study protocol should not be reported. When many hypotheses tests are performed on data from a single study, a number of positive results can be expected to arise by chance alone, creating serious problems of interpretation.
13. Recognizing that a statistically significant association does not in itself provide direct evidence of causal relationship between the variables concerned and that causation can only be established on nonstatistical grounds, particular care should be taken when comparing two variables that have changed over time. Such comparisons often produce apparent associations.
14. Graphic display of results and figures that show individual observations are to be encouraged. For example, when appropriate, fixed regression lines should be presented together with a scatter diagram of the raw data. Any complex statistical methods should be communicated in a manner that is comprehensible to the reader.
15. Rigorous scientific objectivity should be the standard when reporting on epidemiological results. Defects in study design, conduct and analysis should be frankly admitted. It is helpful for abstracts accurately to reflect any study deficiencies. Advocacy and objectivity rarely comfortably coexist.

Sullivan (PM Corporate Services Brussels) announced, “the GEP project would be halted as previously discussed because the [PM IARC] Task Force agreed that it could be counterproductive.”⁸³ PM’s planned long-term “sound science” coalition is now likely to be the Cambridge-based European Science and Environment Forum, which sought funding from tobacco companies in addition to PM for its 1996 inception and has actively criticized the IARC study.⁴⁷

PM still sought official European Union endorsement of GEP, which other industries were already seeking,⁵⁹ and PM hoped it would contain “the necessary language to catch the IARC study.”⁷⁷ In July 1994, PM had a draft of a possible European Union GEP resolution,⁵⁴ and Covington & Burling lawyer John Rupp drafted a European Council resolution about GEP for PM’s consideration.⁸⁴ In early 1995, PM was considering holding a GEP seminar in Germany and introducing PM’s GEP at an October 1995 conference on the use of science in public health regulations to be funded by the European Union’s Directorate General V (Employment, Industrial Relations and Social Affairs) and the nonferrous metal industry.⁸⁵

In September 1995, Joanna Sullivan (PMCS Brussels) wrote to Richard Carchman (director, Scientific Affairs, PM USA) stating that the SH&B GEP guideline revision⁷¹ “should be given to Professor [Ernst] Wynder for passing onto Dr [Henriette] Chamouillet of DGV of the European Commission.”⁸⁶ Wynder, whose early work linked smoking and cancer, had developed a financial relationship with the tobacco industry.^{87–99} PM described Wynder as “being in favor of the [GEP] proj-

ect” and helping PM organize a GEP conference.¹⁰⁰

It is unclear whether Wynder and Chamouillet did indeed meet, but by late 1995, the European Union Data Protection Directive was adopted, stating that “the Commission shall encourage the drawing-up of codes of conduct [for studies involving the processing of medical data]” and that “the Commission may ensure publicity for [approved] codes.”^{101,102} This European Union directive led to a new GEP proposal, drafted in 1995, with limited distribution in 1997, by a group of European and American epidemiologists from industry and academia, in hopes of international review and subsequent European Union Working Group approval.¹⁰¹ Despite PM’s efforts, no European Union resolution on GEP had been produced as of mid-2000.

WORLDWIDE SEMINARS ON GOOD EPIDEMIOLOGY PRACTICES

From 1994 to 2000, seemingly independent seminars on GEP have been conducted by several organizations in the United States, United Kingdom, European Union, and China. In fact, PM is connected to all these events.

Federal Focus, Inc, a nonprofit foundation based in Washington, DC, that engages in research and education pertaining to federal government policy issues, conducted 2 seminars¹⁰³ on epidemiology and risk assessment that appear to have been part of PM’s GEP program. In 1994, Federal Focus convened a 19-member panel in the United States that advocated uniform epidemiology principles.¹⁰⁴ In October 1995, a second 18-member panel met in

London, England, and drafted the “Principles for Evaluating Epidemiologic Data in Regulatory Risk Assessment,” or “London Principles,”¹⁰⁵ which pose a series of questions to guide a risk assessor about the overall quality of the data and its potential weight for a risk assessment. The panel comprised scientific representatives from academia and industry, including some who had received tobacco industry funding or served as tobacco industry consultants.^{47,105,106}

The London Principles do not criticize relative risks of less than 2, but the Federal Focus leaders have, while working under contract with PM. Federal Focus received at least \$200 000 from PM in 1993.¹⁰⁷ Federal Focus’ chairman, Jim Tozzi of Multinational Business Services, was under contract with PM for \$40 000 a month in 1993 and up to \$610 000 in 1994.^{108,109} Thorne Auchter, director of Federal Focus’ Institute for Regulatory Policy, has testified to the US Occupational Safety and Health Administration Public Meeting on Standards Planning Process that “a determination needs to be made regarding the reliability of relative risks in the “weak association (RR<2.0–3.0) range.”¹¹⁰ In 1993 and 1994, Tozzi was to work with PM “to develop materials designed to intensify the debate on the need for scientific standards on meta-analysis and epidemiology such as electromagnetic fields, chlorinated water, and radon in water,” with the purpose of “supporting legislative mandates on epidemiological standards” and “increasing debate on ETS risk assessment within EPA.”¹⁰⁸

PM, Covington & Burling, and Tozzi collaborated on 8 “Criteria for Epidemiology” of which “all

guidelines for conducting epidemiological studies should incorporate consideration,” including “[d]oes the relative risk fall into the realm of ‘weak association’ (RR<2.0–3.0) relative to background?”¹¹¹ In July 1995, Tozzi sought PM to discuss the Federal Focus “EPI Principles” from the “first conference” with NATO and IARC officials, as “EPA, through IARC and NATO, continues to market its indoor air quality program overseas.”¹¹²

The Weinberg Group, a consultancy run by Myron Weinberg that testifies for the tobacco industry on clean indoor-air issues,⁶³ worked with PM to conduct “Good Risk Management Practices” conferences in Europe and Asia. An October 1997 European conference, “The Challenges of Responsible Good Risk Management Practices,” included PM as one of 11 corporate supporters with official sponsorship by the European Union Commission.¹¹³ The speakers included tobacco industry consultant Ragnar Rylander⁶³ (who has consulted for PM about GEP’s utility,^{114,115} stated that relative risks of less than 2 have severe methodological problems,¹¹⁶ and advocated GEP at a 1996 scientific conference¹¹⁷) and the European Science and Environment Forum’s executive director, Roger Bates.¹¹³ Government administrators were session moderators, which Weinberg described to PM as a “valuable concept” because they were “the target of the expert presentations.”¹¹³ PM wanted to repeat a similar Weinberg seminar in Asia in 1998, to be endorsed by the Association of South East Asian Nations,¹¹³ which PM expected to establish guidelines for risk assessment.¹¹⁸ PM planned to commit \$220 000¹¹³ for a conference in Kuala Lumpur or Bangkok by

November 1998 and hoped for published journal articles or conference proceedings.¹¹⁸

The tobacco industry's Center for Indoor Air Research cohosted a July 1997 "International Workshop on Risk Assessment and Good Epidemiological Practices" in China with the Guangzhou Institute for Chemical Carcinogens and the Chinese Epidemiological Association.¹¹⁹ (The Center for Indoor Air Research financed projects "specially reviewed" by tobacco industry lawyers, as opposed to its peer-reviewed projects; the former are more likely to conclude that second-hand smoke does not cause disease.^{120,121}) The China conference brought together 100 lung cancer specialists within China¹²² with a few scientists from outside China, including scientists funded by the tobacco industry.^{47,63,106,123} This China GEP workshop was part of the tobacco industry's "Asia-specific IARC preparation,"¹²⁴ and PM hoped to produce GEP resolutions by Chinese science organizations.¹²⁵ An organizer of the conference coauthored a paper on GEP and the etiology of lung cancer¹²⁶ with industry consultant Joseph Wu,¹⁰⁶ who had been paid \$235 000 in 1995 and 1996 to organize and conduct "Chinese projects" through SH&B.¹²⁷ Wu authored an accompanying editorial¹²⁸ on risk assessment and GEP in the *Chinese Journal of Epidemiology* that states that relative risks of less than 2 may be artifactual for secondhand smoke studies, and that scientists need to examine other factors, such as pollution and diet, for lung cancer.¹²⁸

Several European epidemiologic societies have developed GEP guidelines, including the International Epidemiological As-

sociation (IEA),¹²⁹ the Danish Society of Epidemiology,¹²⁹ and the Association des Epidémiologistes de Langue Française (ADELF, Association of French-Speaking Epidemiologists).¹³⁰ PM may have sought to participate in these processes; John Rupp, the lawyer from Covington & Burling who had drafted a European Council GEP resolution for PM,⁸⁴ lobbied ADELFF on GEP, as well as in Italy and Germany.^{131,132} The ADELFF and IEA epidemiologists who headed the GEP efforts for their organizations state that they had no idea that PM had such subversive intentions. The GEP guidelines developed by the epidemiologic societies do not discuss relative risks of less than 2, and the IEA guidelines emphasize the ethical conduct of epidemiologic studies.

CHANGES IN PHILIP MORRIS'S GOOD PRACTICE PROGRAM

By April 1998, PM began to scale back its GEP program. Ted Sanders (PM Worldwide Scientific Affairs), who was to inherit the GEP program, expressed concern about the GEP program's value to Cathy Ellis (senior vice president of research and development, PM USA):

... the concept of GEPs was discussed in considerable detail in PM. *Corporate Affairs* thought it was a wonderful idea, because at first they ... felt that part of a code for Good Epidemiological Practices would state that any relative risk of less than 2 would be ignored. This is of course not the case. No epidemiological organization would agree to this, and even *Corporate Affairs* realizes this now [emphasis added].¹³¹

Sanders describes PM's initial objective as to discredit epidemiologic results with relative risks

of less than 2, but the company realized that no epidemiological organization would agree to such a standard. Sanders' memo also suggests that if PM had succeeded in securing a GEP code as initially planned, there was a good chance PM would not be able to criticize future errors in epidemiologic studies, and a better alternative would be to continue developing GEP with other companies. PM seems to have followed Sanders' advice; by July 20, 1998, "no further work was to be done on GEP's" by Rupp, who had continued his activities in France.¹³¹

GEP has most recently been a focus for Toxicology Forum, a nonprofit organization that fosters interaction between scientists in academia, government, and industry.¹³³ The 1999 Brussels conference included "Epidemiology in a Policy and Regulatory Context: Considering a Code of Good Epidemiology Practice," and the May 2000 Brussels conference discussed "Determinants and Structure of Guidelines of Epidemiological Practice."¹³³ (Note: When the referenced Website was accessed on September 24, 2001, the title of the May 2000 conference had been changed to "Comparison of the Principles and Practice of Risk Assessment Performed at the Global and European Level," and the list of pending participants had been removed.) The May 2000 session speaker list included tobacco industry consultants.^{63,133-135} PM, R.J. Reynolds, and the Tobacco Institute contributed \$35 000 through Covington & Burling for a 1992 Toxicology Forum meeting¹³⁶ that included the session "Weak Epidemiological Associations and the Limitations of Meta-Analysis."¹³⁷ The international discus-

sion of GEP continues, although the tobacco industry's interest in the 1999 and 2000 GEP Toxicology Forum conference remains unclear.

DISCUSSION

PM appropriated the "sound science" concept to shape the standards of epidemiology and to prevent increased smoking restrictions. The "sound science" coalition was viewed by PM and its public relations firms as a launching point to introduce the tobacco industry version of "good epidemiological practices" that would be accepted by the scientific community. The "sound science" coalitions are similar to other tobacco industry front groups used as third-party spokesmen without disclosing the tobacco industry's involvement.¹⁸⁻²¹ PM's GEP was constructed by their lawyers and internal scientific resources. To gain support for its GEP programs and perspectives, PM capitalized on the concerns of other industries facing regulation and the good intentions of the scientific community, which sought to improve the conduct of epidemiology.

PM has gone beyond "creating doubt"⁶³ and "controversy"^{120,121} about the scientific evidence that demonstrates that active and passive smoking cause disease, to attempting to change the scientific standards of proof. PM's higher level of activity in Europe with GEP reflects the reason for this strategy shift. PM sought to establish a tactically advantageous scientific and policy-making environment before a scientific threat materialized in Europe, whereas in the United States, PM was reacting against an already damaging scientific government publication. The versions of GEP PM

and its allies promoted discount relative risks below 2 and would set the standard in such a way that would make it impossible to conclude that secondhand smoke, as well as many other environmental toxins, is dangerous.

This approach ignores the fact that a comprehensive assessment of risk involves considering all the evidence related to a toxin, not just the epidemiology. This distinction was highlighted in the response to a news article in *Science*,¹³⁸ which represented several epidemiologists as concluding that there was a high threshold for a relative risk's being worth considering.¹³⁹ One of the epidemiologists quoted in the article responded that the news story

... writes that I have expressed the view that only a fourfold risk should be taken seriously. That is correct, *but only when the finding stands in a biological vacuum or has little or no biological credibility*. We all take seriously small relative risks when there is a credible hypothesis in the background. Nobody disputes that the prevalence of boys at birth is higher than that of girls (an excess of 3%), that men have a 30% higher death rate compared with women of the same age, or that fatality in a car accident is higher when the car is smaller [emphasis added].¹⁴⁰

The risks mentioned are similar in magnitude to (or smaller than) the risks associated with secondhand smoke.

The industry's strategy for dealing with secondhand smoke may be shifting again. In 2000, PM released a Web site that acknowledges that many scientific studies report a small increased risk in disease with secondhand smoke exposure, but also claims that "exposure levels outside the home are lower than regulators have generally assumed."¹⁴¹

These claims of inconsequential exposures are based on tobacco industry-funded studies of dubious accuracy that were carried out within the same construct as the GEP efforts and other efforts to subvert the scientific process. Indeed, the pilot studies for these exposure studies have been demonstrated in government proceedings to be unreliable.⁴⁷

As greater understanding of the tobacco industry's subversive operations accumulates, scientists and policymakers face the question of whether or not to include the tobacco industry in their discourses. Pros and cons of publishing any material funded by the tobacco industry have been debated, and some journals and organizations have rules to exclude those who are funded by the tobacco industry.¹⁴²

The World Health Organization's tobacco control effort is the most prominent global case to observe in the near future, as the WHO deals with both the scientific and policy-making worlds and has been targeted by the tobacco industry. The WHO recently published a special inquiry on the tobacco documents, which concluded that the tobacco industry views the WHO as one of its leading enemies and strategized to "contain, neutralise, reorient" WHO's tobacco control initiatives.¹⁴³ The WHO is also conducting hearings, which include the tobacco industry, for its international Framework Convention on Tobacco Control. (Uncannily similar to projects of the TASSC and to Junkscience.com, a Web site for Guest Choice Networks, which claims to represent more than 30 000 restaurant and tavern owners in promoting consumer choice, proclaims the WHO's Framework Convention as "Junk Science Goes Global."¹⁴⁴)

Publicly, the tobacco industry is now shifting to a campaign touting responsible corporate citizenship^{145,146} and nominal efforts purportedly to discourage youth smoking prevention.¹⁴⁷ The industry's many past efforts—beginning with the "Frank Statement" advertisement and creation of the Tobacco Industry Research Committee in the United States in 1954^{63(pp32–44)}—to publicly reinvent itself, while privately doing everything it can to protect itself from meaningful regulation and maximizing sales and profits, suggest that the WHO (and other government and scientific bodies) maintain an arm's-length relationship with the tobacco industry until it visibly reduces its aggressive efforts to promote tobacco use, whether to children or adults, worldwide.

Because the US Supreme Court is allowing judges more freedom to decide whether to admit or exclude scientific evidence,^{148,149} the question of what work constitutes "junk science" or "sound science" comes to the forefront in discussions of the health effects of industry products and activities. Discussions of how to improve epidemiology should be ongoing, although there is continued debate as to the necessity for epidemiologic guidelines.^{150,151} While every practicing scientist agrees that scientific work should be rigorously done, the scientific, public health, and regulatory communities need to be more aware that the "sound science" and "GEP" movement is not simply an effort from within the profession to improve the quality of scientific discourse. This movement reflects sophisticated public relations campaigns controlled by industry executives and lawyers to manipulate the scientific standards of

proof for the corporate interests of their clients. ■

About the Authors

The authors are with the Institute for Health Policy Studies, University of California, San Francisco. Stanton A. Glantz is also with the Department of Medicine, Division of Cardiology.

Requests for reprints should be sent to Stanton A. Glantz, PhD, Department of Medicine, Division of Cardiology, Box 0130, University of California, San Francisco, CA 94143–0130 (e-mail: glantz@medicine.ucsf.edu).

This commentary was accepted April 6, 2001.

Contributors

E. K. Ong performed the document research. Both E. K. Ong and S. A. Glantz prepared and revised the manuscript.

Acknowledgments

This work was supported by National Cancer Institute grants CA-61021 and CA-87472 and the Richard and Rhoda Goldman Fund.

The authors would like to acknowledge Paolo Boffetta, Rodolfo Saracci, Marcus Goldberg, and Jorn Olsen for their helpful discussions, and Norbert Hirschhorn and Stella Aguinaga Bialous for providing several relevant references.

References

- Hollingsworth P. The "junk science" dilemma. *Am Scientist*. 2000; 88:2–4.
- Huber P. *Galileo's Revenge: Junk Science in the Courtroom*. New York, NY: Basic Books; 1991.
- Schwartz J. Only good science to keep on debating "junk science." *Houston Chronicle*. March 28, 1999:5
- Price J, Svitak L. It's time we took "junk science" out of the courtroom. *Star-Tribune* [Minneapolis]. June 20, 1999:5D.
- Price J, Rosenberg E. The war against junk science: the use of expert panels in complex medical-legal scientific litigation. *Biomaterials*. 1998;19: 1425–1432.
- McCullough L. Two views on Europe's ban of US beef: beef ban based in social issues, not sound science. *Wisconsin State Journal*. July 18, 1999:2B
- Luik J. Toronto smoking debate fogged by junk science. *National Post* [Toronto]. July 8, 1999:C7
- Crane M. Is "junk science" finally on the way out? *Med Econ*. 1996;73: 59–61, 65–66.

9. Pear R. Research web site idea fuels junk-science fears. *San Diego Union-Tribune*. June 16, 1999:E3
10. Fenske R. Pesticide limits based on sound science. *Seattle Times*. August 5, 1999:B4.
11. Coggon D, Cooper C. Fluoridation of water supplies: debate on the ethics must be informed by sound science. *BMJ*. 1999;319:269–270.
12. Kizer K, Warriner T, Book S. Sound science in the implementation of public policy: a case report on California's Proposition 65. *JAMA*. 1988;260:951–955.
13. Reinken J. *Through the Smoke-screen—A Critique of Environmental Tobacco Smoke: A Review of the Literature by the Tobacco Institute of New Zealand*. Wellington: New Zealand Department of Health; 1990.
14. Bero L, Glantz S. Tobacco industry response to a risk assessment of environmental tobacco smoke. *Tob Control*. 1993;2:103–113.
15. Benitez JB, Idle JR, Krokan HE, et al., eds. *Environmental Tobacco Smoke and Lung Cancer: An Evaluation of the Risk*. Trondheim, Norway: European Working Group on Environmental Tobacco Smoke and Lung Cancer; 1996.
16. Davey Smith G, Phillips A. Passive smoking and health: should we believe Philip Morris's "experts"? *BMJ*. 1996;313:929–933.
17. *The Health Effects of Passive Smoking*. Canberra, Australia: National Health and Medical Research Council; November 1997.
18. Samuels B, Glantz S. The politics of local tobacco control. *JAMA*. 1991;266:2110–2117.
19. Americans for Nonsmokers' Rights Foundation. The National Smokers Alliance: exposed. Available at: <http://www.no-smoke.org/nsa.html>. Accessed August 27, 1999.
20. Traynor M, Begay M, Glantz S. New tobacco industry strategy to prevent local tobacco control. *JAMA*. 1993;270:479–486.
21. Dearlove J, Glantz S. 1999. Tobacco control policymaking in New York. Institute for Health Policy Studies, University of California San Francisco. February 1999. Available at: <http://www.library.ucsf.edu/tobacco/ny>. Accessed September 24, 2001.
22. Glantz SA. The truth about big tobacco in its own words. *BMJ*. 2000;321:313–314.
23. *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*. Washington, DC: Office of Research and Development, US Environmental Protection Agency; 1992.
24. Merlo E. Memo to William Campbell [re: PM USA ETS actions]. February 17, 1993. Document no. 2021183916/3930. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
25. Lattanzio T. ETS Task Force update. May 20, 1993. Document no. 2021178204. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
26. The Advancement of Sound Science Coalition. [Information sheet describing TASSC.] 1993. Document no. 2046989061. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
27. Kraus M. [Letter to PM Director of Communications re: TASSC]. September 23, 1993. Document no. 2024233677/3682. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
28. PM USA. Corporate Affairs 1994 budget presentation. October 21, 1993. Document no. 2046847121. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
29. Kraus M, Cohen N, Hockaday T. Revised 1993 TASSC launch program. October 15, 1993. Document no. 2045930491. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
30. Kraus M. [Memo to Matt Winokur re: TASSC briefing.] October 26, 1993. Document no. 2025840783/0784. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
31. TASSC. The Advancement of Sound Science Coalition Member Survey. 1993. Document no. 2024233662/3663. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
32. Lister C. Memorandum to Dr. Reif Re: tolerance and junk science. February 2, 1993. Document no. 2028359740/9742. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
33. Hockaday T. Update on the activities of The Advancement of Sound Science Coalition (TASSC). July 1, 1993. Document no. 2024233614. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
34. The Advancement of Sound Science Coalition. Table of contents: TASSC—direct mail membership recruitment mailings. 1993. Document no. 2046989020. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
35. National watchdog organization launched to fight unsound science used for public policy decisions. *US Newswire*. November 24, 1993.
36. Sound Science Coalition names former congressman Mickey Edwards to lead advisory committee. *PR Newswire*. August 16, 1995.
37. Science watchdog group celebrates third anniversary with renewed commitment to exposing use of junk science. *PR Newswire*. December 3, 1996.
38. Helvarg D. The big green spin machine: corporations and environmental PR (public relations). *Amicus Journal*; Summer 1996;18(2):13–21.
39. Kraus M. Sound science/lindheim meeting/next steps. April 26, 1994. Document no. 2025493192/3194. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
40. Lenzi J. TASSC update. November 15, 1993. Document no. 2024233664. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
41. Andrade A. The Advancement of Sound Science Coalition (TASSC). October 1, 1993. Document no. 2024233656. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
42. Merlo E. TASSC. April 29, 1994. Document no. 2024233594. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
43. Office of Victor Han. 1994 Communications plan. 1994. Document no. 2023918833/8852. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
44. Office of David Cooper. Consumer issues program. October 1995. Document no. 2046039179/9194. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
45. Levy R, Marimont R. Lies, damned lies, and 400,000 smoking-related deaths. *Regulation*. 1998;21:24–29.
46. Milloy S. JunkScience.com. Available at: <http://www.junkscience.com>. Accessed March 10, 2000.
47. Ong E, Glantz S. Tobacco industry efforts to subvert a secondhand smoke study by the International Agency for Research on Cancer. *Lancet*. 2000;355:1253–1259.
48. Boffetta P, Agudo A, Ahrens W, et al. Multicenter case-control study of exposure to environmental tobacco smoke and lung cancer in Europe. *J Natl Cancer Inst*. 1998;90:1440–1450.
49. Sullivan J. IARC study. September 2, 1993. Document no. 2501117793/7797. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
50. Winokur M. IARC situation overview and plan: presentation to PMCS. April 13, 1994. Document no. 2501355931/5944. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
51. Hockaday T, Cohen N. Thoughts on TASSC Europe. March 25, 1994. Document no. 2024233595/5602. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
52. Burson-Marsteller. Assessment project: Scientists for Sound Public Policy. March 1994. Document no. 2025493130/3138. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
53. Lindheim J. Scientist group in Europe. April 18, 1994. Document no. 2025493128/3129. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
54. Winokur M. IARC TF. July 5, 1994. Document no. 2028380422/0467. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
55. Burson-Marsteller. Scientists for Sound Public Policy: assessment project and symposium. 1994. Document no. 2028363773/3791. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
56. Cook R. Overview of good epidemiologic practices. *J Occup Med*. 1991;33:1216–1220.
57. Chemical Manufacturers Association. Guidelines for good epidemiology practices for occupational and environmental epidemiologic research. 1991. Document no. 2024005575/5604. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
58. Chemical Manufacturers Association's Epidemiology Task Group. Guidelines for Good Epidemiology Practices for occupational and environmental epidemiologic research. *J Occup Med*. 1991;33:1221–1229.
59. Lister C. Memorandum to Messrs. Winokur and Bushong Re: epidemiological standards. February 24, 1994. Document no. 2026221042. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
60. Walk R. Quality assurance in epidemiology: GEP. November 1996. Document no. 2063604594/5600. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
61. Borrelli T. GEP review. March 15, 1994. Document no. 2028446631B. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.

62. Barnes D, Hanauer P, Slade J, Bero L, Glantz S. Environmental tobacco smoke. *JAMA*. 1995;274:248–253.
63. Glantz S, Slade J, Bero L, Hanauer P, Barnes D. *The Cigarette Papers*. Berkeley: University of California Press; 1996.
64. Ritter M. GEP proposal. March 17, 1994. Document no. 2028446632. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
65. Reif H. GEP review. March 17, 1994. Document no. 2028446631. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
66. Office of RA Walk. IARC tools. 1994. Document no. 2029059645. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
67. Hockaday T. 17 Guiding Scientific Principles from The Advancement of Sound Science Coalition (TASSC). June 15, 1994. Document no. 2025492907/2909. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
68. Winokur M. Sound science activities. June 16, 1994. Document no. 2025493118A/3119. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
69. Sheehan T, Cameron C. Epidemiologic proof of causation. *For the Defense*. 1999:34–39.
70. Winokur M. [Roger Walk's revised GEP resolution.] July 26, 1994. Document no. 2028381639. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
71. Walk R. Proposed guidelines for Good Epidemiology Practices. July 25, 1994. Document no. 2029260524/0539. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
72. *The Health Consequences of Involuntary Smoking*. Report of the Surgeon General. Washington, DC: Office of the Assistant Secretary of Health, Office of Smoking and Health; 1986. DHHS publication PHS 87-8398.
73. *Effects of Passive Smoking on Health*. Canberra, Australia: National Health and Medical Research Council; June 1986.
74. *Health Effects of Exposure to Environmental Tobacco Smoke*. Sacramento: California Environmental Protection Agency; 1997.
75. Report of the Scientific Committee on Tobacco and Health. March 1998. Available at: <http://www.officialdocuments.co.uk/document/doh/tobacco/report.htm>. Accessed September 24, 2001.
76. He J, Vupputuri S, Allen K, Prerost M, Hughes J, Whelton P. Passive smoking and the risk of coronary heart disease—a meta-analysis of epidemiologic studies. *N Engl J Med*. 1999;340:920–926.
77. Sullivan J. IARC next meeting. June 15, 1994. Document no. 2025493426/3427. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
78. Lindheim J. Re: Scientist project. June 16, 1994. Document no. 2025493117. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
79. Burson-Marsteller. Burson-Marsteller Milan Sound Science Project executive summary. June 17, 1994. Document no. 2025493074/3084. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
80. Albinus S. Re: Sound Science Project and European Seminar in the autumn 1994. June 17, 1994. Document no. 2025493066/3069. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
81. Lister C, Green J. Memorandum to Mr. Bushong re: Sound Science and GEP. August 14, 1994. Document no. 2028381627. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
82. Walk R. IARC Task Force meeting. September 28, 1994. Document no. 2028381446/1447. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
83. Sullivan J. IARC Task Force meeting Brussels. October 4, 1994. Document no. 2028381444. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
84. Winokur M. Draft EU Resolution on GEP. April 12, 1995. Document no. 2050751334. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
85. Walk R. EU GEP Conference. February 6, 1995. Document no. 2028381562. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
86. Sullivan J. GEP. September 27, 1995. Document no. 2050761345. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
87. Bowling J. American Health Foundation. May 22, 1973. Document no. 2015013864. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
88. Wynder E. [Letter to PM USA president concurring animal research not necessarily relevant to smoking and human health.] May 30, 1974. Document no. 1003710586. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
89. Wynder E. [Letter to PM research center head about collaborating in areas of mutual interest.] April 17, 1975. Document no. 1003710876/0877. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
90. Warshaw S. Re: Report on luncheon meeting with Dr. Ernst Wynder of American Health Foundation. June 19, 1974. Document no. 2015013815. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
91. Ruder W. [Letter to Wynder from Ruder & Finn suggesting R&F executive VP for American Health Foundation board and discussing PM as R&F client.] June 27, 1974. Document no. 2015013819/3820. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
92. Ruder W. [Letter to PM stating American Health Foundation press kit by Ruder & Finn has no mention of smoking and health problem.] June 19, 1975. Document no. 2015013901. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
93. Davies D. [Thank you letter to PM president for PM \$20 000 for building fund.] November 4, 1974. Document no. 2015013916. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
94. Osdene T. [Letter re: \$25 000 for American Health Foundation.] October 14, 1986. Document no. 2021630516. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
95. Osdene T. [Letter re: \$25 000 for American Health Foundation.] October 13, 1987. Document no. 2021630797. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
96. Osdene T. [Letter re: \$25 000 for American Health Foundation.] April 18, 1988. Document no. 2021630850. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
97. Osdene T. [Letter re \$25 000 for American Health Foundation.] August 30, 1989. Document no. 2021630898. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
98. Osdene T. [Letter re \$25 000 for American Health Foundation.] October 10, 1990. Document no. 2021630953. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
99. Bruckner E. Re Research project "Epidemiologic Study of Lung Cancer in Japan and the United States." April 10, 1995. Document no. 2050762685. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
100. Monthly Activities HER, S&T, FTR/PM Neuchatel. November 29, 1994. Document no. 2028372914/2915. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
101. Jackson J. Activity in 1998 in the development of standards of good epidemiological practice. *Int Arch Occup Environ Health*. 1999;72:M81–M85.
102. Bloemen L, Jackson J, Kightlinger M, Mundt K, Pastides H. A new proposal for a code of good epidemiological practice. Undated. Document no. 2063605907. Available at: <http://www.pmdocs.com>. Accessed September 4, 2001.
103. Federal Focus Inc. Available at: <http://www.fedfocus.org>. Accessed August 1999.
104. Graham JD. *The Role of Epidemiology in Regulatory Risk Assessment*. Amsterdam, the Netherlands: Elsevier Science; 1995.
105. *Principles for Evaluating Epidemiologic Data in Regulatory Risk Assessment: Developed by an Expert Panel at a Conference in London, England, October 1995*. Washington, DC: Federal Focus Inc; 1996.
106. Office of Thomas Osdene. ETS/IAQ scientific consultants. August 30, 1989. Document nos. 2023483171, 2023483161. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
107. Aucher T. The need for Good Epidemiology Practices (GEPs) in studies used by regulatory agencies. November 21, 1994. Document no. 2050240421/0422. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
108. Fuller C. [Letter to Jim Tozzi re: Federal Focus check.] July 13, 1993. Document no. 2046597569. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
109. Borelli T. [Memo re monthly budget supplement re: ETS/OSHA federal activities.] March 16, 1993. Document no. 2046597148/7150. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
110. Philip Morris Management Corporation. Re agreement dated January 1, 1994. August 8, 1994. Document no. 2029377061/7063. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
111. Winokur M. Epi guidelines. August 25, 1994. Document no.

- 2028381624/1625. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
112. Tozzi J. EPA. July 24, 1995. Document no. 2050761193. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
113. Walk R. Proposed conference on "good risk management practices" in Asia 1998. August 1, 1997. Document no. 2063600682. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
114. Dempsey R. Regarding: Good Epidemiological Practices. March 31, 1994. Document no. 2026221040. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
115. vanHolt K. Re Good Epidemiological Practices. April 25, 1994. Document no. 2026221035. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
116. Rylander R. Low risk epidemiology and good epidemiological practice. No date. Document no. 2050241534. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
117. Etzel R, Windham G, Soskolne C. International Society for Environmental Epidemiology 8th Annual Conference. 1996. Available at: <http://www.iseepi.org/NOFRAMES/96rep.htm>. Accessed June 21, 2000.
118. Worldwide Scientific Affairs. Activities—project summaries. January 9, 1998. Document no. 2060565605/5617. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
119. Zhang M. Press article in the *China Daily* on the CIAR's GEP workshop in Guangzhou. September 29, 1997. Document no. 2063608546. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
120. Barnes D, Bero L. Industry-funded research and conflict of interest: an analysis of research sponsored by the tobacco industry through the Center for Indoor Air Research. *J Health Polit Policy Law*. 1996;21:515–542.
121. Barnes D, Bero L. Why review articles on the health effects of passive smoking reach different conclusions. *JAMA*. 1998;279:1566–1570.
122. Zhu B. Countries unite against cancer. *China Daily*. July 17, 1997. Document no. 2063608547. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
123. Office of Richard Carchman. International Workshop on Risk Assessment and Good Epidemiological Practices. July 14–17, 1997. Document no. 2063608584/8602. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
124. PM Scientific Affairs Hong Kong. Third Meeting of Asian Regional Tobacco Industry Science Team "ARTIST." May 26, 1997. Document no. 2063626181. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
125. Walk R. Support of good science in Asia. October 4, 1996. Document no. 2060565640. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
126. Du Y, Wu J. [Exploration of etiology of lung cancer and good epidemiological practices.] *Chung-Hua Liu Hsing Ping Hsueh Tsa Chih*. 1997;18:367–371.
127. Dreyer L. [Re Dr. Wu's expenses for Shook, Hardy & Bacon.] August 14, 1996. Document no. 2061683610/3620. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
128. Du Y. [Risk assessment and good epidemiological practices.] *Chung-Hua Liu Hsing Ping Hsueh Tsa Chih*. 1997; 18:323–324.
129. IEA/The European Epidemiology Group. Good Epidemiological Practice: proper conduct in epidemiologic research. October 1999. Available at: http://www.dundee.ac.uk/iea/euro_contents.htm. Accessed September 24, 2001.
130. Association des Epidémiologistes de Langue Française. *Recommendations: Professional Standards and Good Practices in Epidemiology*. Lyon, France: December 1998.
131. Sanders E. GEP's. July 20, 1998. Document no. 2060569954/9956. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
132. Rupp J. [Re ADELPH GEP September 1997 version.] October 2, 1997. Document no. 2063658334. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
133. Toxicology Forum. March 10, 2000. Available at: <http://www.toxforum.com/topics.htm>. Accessed March 10, 2001.
134. Philip Morris Europe Science and Technology Neuchatel. ETS plan and budget for the years 1988, 1989, 1990, and 1991. April 19, 1988. Document no. 2028364436. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
135. Covington & Burling. [Re invoice payments for consultants.] 1991. Document no. 2023856353/6357. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
136. Buckley M. [Letter re Toxicology Forum invoice for tobacco industry.] August 7, 1992. Document no. 2024526242. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
137. Toxicology Forum. 1992. Document no. 2028402242. Available at: <http://www.pmdocs.com>. Accessed September 24, 2001.
138. Taubes G. Epidemiology faces its limits. *Science*. 1995;269:164–169.
139. Willett W, Greenland S, MacMahon B, et al. The discipline of epidemiology [letter]. *Science*. 1995;269:1325–1326.
140. Trichopoulos D. The discipline of epidemiology [letter]. *Science*. 1995; 269:1326.
141. Philip Morris USA. Secondhand smoke: our actions to reduce unwanted ETS. 2000. Available at: <http://www.philipmorrisusa.com/DisplayPageWithTopic.asp?ID=62>. Accessed February 2001.
142. King J, Yamey G. Why journals should not publish articles funded by the tobacco industry. *BMJ*. 2000;321: 1074–1076.
143. Tobacco Free Initiative. An introduction to the WHO inquiry on tobacco industry influence. Available at: <http://www.who.int/genevahearings/inquiry.html>. Accessed February 2001.
144. Guest Choice Networks. WHO's fooling who? Junk science goes global. 2000. Available at: http://www.guestchoice.com/0420_junkscience.html. Accessed February 2001.
145. Philip Morris USA. 2000. Our mission and values. Available at: <http://www.philipmorrisusa.com/DisplayPageWithTopic.asp?ID=63>. Accessed February 2001.
146. Philip Morris International. Corporate responsibility. 2000. Available at: http://www.pmintl.com/corp_resp/index.html. Accessed February 2001.
147. Brundtland G. Achieving worldwide tobacco control. *JAMA*. 2000; 284:750–751.
148. Marwick C. Court ruling on "junk science" gives judges more say about what expert witness testimony to allow [news]. *JAMA*. 1993;270:423.
149. Reichhardt T. Court affirms judges' right to reject "junk science" [news]. *Nature*. 1998;391:4.
150. Prineas RJ, Goodman K, Soskolne CL, et al. Findings from the American College of Epidemiology's survey on ethics guidelines. *Ann Epidemiol*. 1998; 8:482–489.
151. Rushton L. Reporting of occupational and environmental research: use and misuse of statistical and epidemiological methods. *Occup Environ Med*. 2000;57:1–9.